

Serial No.: 10/591,438
Atty. Docket No.: P71416US0

REMARKS

The Office Action mailed January 16, 2008, has been carefully reviewed and, by this Amendment, Applicant has canceled claims 1-23 and added claims 24-43. Claims 24-43 are pending in the application. Claims 1 and 34 are independent.

As an initial matter, Applicant has amended the abstract and specification to better conform with U.S. practice.

The Examiner rejected claims 1-3, 5, 6, 14-18 and 23 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,690,622 to Smith et al. ("Smith '622"). Under 35 U.S.C. 103(a), the Examiner rejected claims 7-13 as being unpatentable over Smith, rejected claim 4 as being unpatentable over Smith '622 in view of U.S. Patent No. 5,840,073 to Olsen, rejected claim 19 as being unpatentable over Smith '622 in view of U.S. Patent No. 5,591,144 to Smith et al. ("Smith '144"), rejected claim 20 as being unpatentable over U.S. Patent No. 5,938,647 to Smith ("Smith '647"), rejected claim 21 as being unpatentable over Smith '622 in view of Smith '144 and further in view of Smith '647, and rejected claim 22 as being unpatentable over Smith '647 in view of U.S. Patent No. 4,917,689 to Coombes.

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With the cancellation of claims 1-23, the rejections are technically moot. However, in regard to new claims 24-33, Applicant provides the following remarks.

As set forth in new claims 24 and 34, the present invention is directed to an ostomy system for receiving bodily waste that includes a gas impermeable outer bag, a water impermeable inner bag enclosed within the outer bag, and a coupling system for attaching the bag to the body of a patient, the coupling system defining an orifice to enable bodily waste from a stoma to be received by the inner bag.

More particularly, the coupling system includes a body flange that is configured to be attached to the patient's body and which defines a central opening with an inwardly facing rim portion, an outer flange that defines a central opening with an inwardly facing rim portion, and a barrier to prevent liquids and solid particles from passing from the inner bag to the outer bag. At least part of the barrier is permeable to flatus gases. The barrier, which is in the form of a ring-shaped member that defines a central opening with an inwardly facing rim portion, *is sandwiched between the body flange and the outer flange* such that the respective radially inwardly facing rim portions of the body flange, the barrier and the outer flange define a boundary of the

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orifice so that the flatus gases enter the barrier through the radially inwardly facing rim portion thereof.

Finally, the inner bag is sealed to an outer surface of the outer flange, so that flatus gases may only escape from the inner bag through the barrier, while the gas impermeable outer bag is arranged such that flatus gases escaping the inner bag through the barrier enter the outer bag. The outer bag includes an outlet with a flatus filter for releasing flatus gases from the outer bag to the environment. The foregoing structure is not shown or suggested by the prior art.

Smith '622 discloses an ostomy bag for receiving bodily waste having a water-impermeable inner bag 1 within an outer bag 2. The inner bag 1 has an opening 15 above the level at which waste enters the bag through orifice 6. The opening 15 is covered by a disc 16 made of a hydrophobic, gas-permeable foam material that is secured to the wall of the inner bag. The disc 16, or barrier, allows flatus gas to pass therethrough while preventing the passage of liquids.

As disclosed in Smith '622, the disc barrier 16 is not at all part of a coupling system that attaches the bag to the patient as claimed by the present invention. Nor can the disc barrier 16 of Smith '622 be said to have a *ring-shaped* construction that is

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sandwiched between a body flange and an outer flange of the coupling system, as also set forth in claim 1 (for support, see page 7, lines 11-13 of the specification and Figures 1 and 5). On the contrary, the disc covering the opening 15 is completely separate from the bag coupling structure and is merely attached to the outer surface of the inner bag (see Figure 4 of Smith '622). Further, there is nothing in the Smith '622 structure that would begin to suggest the coupling system and barrier member as claimed by the present invention.

For at least the foregoing reasons, claims 24 and 34 are patentable over Smith '622. The secondary references of Smith '144, Smith '647, Olsen and Coombes also do not disclose any structural features that would teach or suggest the claimed invention. Favorable consideration and allowance of claims 24 and 34 is requested.

Claims 25-33 and 35-43 are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein.

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance.

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Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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